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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,957	07/21/2004	Samuel G. Steinemann	09307.2003-00000	8443

21127 7590 03/27/2008  
RISSMAN JOBSE HENDRICKS & OLIVERIO, LLP  
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BOSTON, MA 02114

EXAMINER
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KENNEDY, SHARON E

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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03/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,957	<b>Applicant(s)</b> STEINEMANN ET AL.	
	<b>Examiner</b> Sharon E. Kennedy	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/03/2004; 10/13/2004</u> .                                  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims include ranges within ranges by use of terms such as “preferably,” etc. See claim 28, for example. This is not permitted in U.S. practice and must be corrected. For further information, see MPEP 2173.05(c). The claims will be examined as if the embodiments following the phrases “preferably” were not present.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28-34, 42-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Copf, DE 19949890. Applicant's claims are directed to an osteogenic implant comprising a titanium metal and having a portion of the surface covered with a particular polypeptide as recited in the ranges. The partial covering is achieved, as explained in applicant's published paragraph [0039], by the particular chemical composition of the

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metal surface, the pretreatment thereof, etc. The surface of the titanium, in other words, is partially hydroxylated, so that a combination of the two effects of roughening is achieved. Regarding the macro and micro roughness, applicant explains that the macro roughness can be very macro, such as the screw thread on a tooth implant [0015], or achieved by a combination of the various roughening techniques as explained in the specification.

Copf discloses the identical surface roughening treatments used alone or in combination with various other methods. These are the same methods disclosed by applicant. Copf also discloses macro openings as the “through openings 72 formed by drilling” (page 3, lines 6+), which meets the definitions of macro roughness set forth in applicant’s specification. Copf also discloses the micro roughness being formed by the chemical etching, sand blasting, etc. The examiner again notes the similarities between applicant’s published paragraph [0018] and the roughness finishing methods of Copf.

Accordingly, the only difference between the claimed invention and Copf is that applicant has examined the surface of the implant as set forth in applicant’s [0039] and characterized the amount of covering density. Applicant does not appear to have set forth any unusual aspect regarding this characterization, or discovered an optimum range in comparison to others. Copf does not explicitly disclose the resulting coating density, however, the examiner takes the position that the coating density is either the same or very similar in view that the method steps are the same. Accordingly, the invention is obvious in view of Copf unless applicant can make a showing of unexpected results achieved from the particular ranges. At this point, it merely seems if applicant

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has simply examined and determined the ranges of the prior art methods. Regarding claims 50, 51, Copf discloses ankle joints, however, clearly the preparation process is applicable to any insertable osteogenic implant. Regarding the packaging, it is well known that implants are maintained in sealed, sterile packages which facilitate long term storage of the properties applied to the implants.

Claims 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Copf in view of Atkinson et al., US 6,511,958. Applicant requires specific osteocalcin embodiments, etc., with the implant. Copf discloses that substances may be used which promote bone growth, including BMP. Atkinson exemplifies that the recited osteogenic growth peptides and BMP proteins are commonly used with implants. It would be obvious to one of ordinary skill in the art to include the art recognized peptides for their intended purposes in the lack of a showing of surprising results.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Sharon E. Kennedy/*

Sharon E. Kennedy  
Primary Examiner  
Art Unit 1615